The Pragmatic Airway Resuscitation Trial

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McGovern Medical School at UTHealth
Disclosures

• NIH Grant Support
  • UH2/UH3-HL125163

• PI, Pragmatic Airway Resuscitation Trial
What is Bag-Valve-Mask Ventilation?
What is Endotracheal Intubation?
What is EMS?

- Emergency Medical Services
- Emergency acute care
- Rapid assessment, stabilization, triage
- Transport to receiving hospital
- Uncontrolled prehospital environment
System of US EMS Care

• Basic Life Support (BLS) Emergency Medical Technician (EMT)
  • CPR
  • Bag-valve-mask ventilation
  • Automated external defibrillators
  • No intubation or drugs

• Advanced Life Support (EMS) Paramedic
  • Intubation
  • IV medications
  • Manual defibrillation

• Few EMS physician systems in US
Why Intubate in the Field?

• Provide direct conduit to lungs
• Improve ventilation
• Prevent aspiration
• Parallels in-hospital care
• Ultimate goal → “Save lives”
“Does Prehospital Intubation Improve Outcomes (Save Lives)?”
Does Intubation Save Lives?

• >20 studies of prehospital intubation and outcome (survival)

• Recurrent theme:
  • Prehospital intubation associated with *increased* risk of death
  • Prehospital intubation associated with *poorer* neurological outcome
Prehospital Intubation of Children

- Gausche, JAMA 2000
- RCT
- [BVM ± ETI] vs. BVM-only
- 830 children

- No difference in survival
- No difference in neurological outcome
“Are Poor Outcomes Due to Errors?”
Endotracheal Tube Misplacement

• Katz and Falk, Annals Emerg Med 1999
• N=108 prehospital intubations
  • Systematic reconfirmation in ED
• 25% tube misplacement rate
  • 2/3 esophageal
  • 1/3 above vocal cords
Oxygen Desaturation and Bradycardia

- Dunford, Annals Emerg Med 2004
- San Diego RSI Trial
- N=152 RSI patients
- Continuously recorded waveforms:
  - Heart Rate
  - Oxygen Saturation
  - End-Tidal Capnography
Oxygen Desaturation and Bradycardia

Oxygen Desaturation and Bradycardia

Oxygen Desaturation: 31 (57%)
Bradycardia: 6 (19%)

“Does Intubation Interact with Other Interventions?”
CPR Chest Compressions

- ACLS Guidelines:
  - “Avoid CPR Chest Compression Interruptions”

- New CPR detection technology
  - Can “see” delivered chest compressions
Example of CPR Interruption from Intubation
Example of CPR Interruption from Intubation

ETCO$_2$ Signal
Example of CPR Interruption from Intubation

ET Tube Placement

ETCO₂ Signal

ET Tube Placement
Example of CPR Interruption from Intubation

ET Tube Placement

30 sec CPR Interruption

ETCO₂ Signal

ET Tube Placement
Intubation-Associated Chest Compression Interruptions

- Wang, Annals EM 2009
- Pittsburgh
- N=100
- Review of CPR process files and audio recordings
- Identified all CPR interruptions due to intubation efforts
Intubation-Associated CPR Interruptions

Pittsburgh, n=100
Now, consider the impact of intubation on CPR interruptions. Wang et al. (2009) examined 100 patients in Pittsburgh and found that intubation was associated with a median of 2 CPR interruptions (IQR: 1-3), ranging from min 1 to max 9. Interestingly, 30% of patients experienced more than 2 interruptions during intubation.

This highlights the critical need for streamlined protocols to minimize interruptions and improve cardiac arrest outcomes.
Duration of Intubation-Associated CPR Interruptions

Duration of Intubation-Associated CPR Interruptions

First CPR Interruption
Median: 46.5 sec (IQR: 23.5-73)
Min 7, Max 221
~30% >60 sec

Duration of Intubation-Associated CPR Interruptions

First CPR Interruption
Median: 46.5 sec (IQR: 23.5-73)  
Min 7, Max 221  
~30% >60 sec

Subsequent CPR Interruptions
Median: 35 sec (IQR: 21-58)  
Min 7, Max 199  
~20% >60 sec

Duration of Intubation-Associated CPR Interruptions

First CPR Interruption
Median: 46.5 sec (IQR: 23.5-73)
Min 7, Max 221
~30% >60 sec

Subsequent CPR Interruptions
Median: 35 sec (IQR: 21-58)
Min 7, Max 199
~20% >60 sec

Sum of All CPR Interruptions
Median: 109.5 sec (IQR: 54-198)
Min 13, Max 446
~25% >180 sec

“Does Training Play a Role?”
Intubation is Difficult in Prehospital Mosh Pit

“There’s no such thing as an easy prehospital airway”

“Paramedics need exceptional intubation skills”
How Many Intubations Do You Need to Graduate in the US?

- Emergency Med Residents: 35
- Anesthesia Residents: 20-57
- CRNA Students: 200
- Paramedic Students: 5
Paramedic Student Operating Room Training Hours

Johnston, et al., Acad Emerg Med 2006
Paramedic Student Operating Room Training Hours

- Median 17-32 hours

Johnston, et al., Acad Emerg Med 2006
Paramedic Student Operating Room Barriers

• Competition from other students
• Widespread Laryngeal Mask Airway use
• Anesthesiologists’ medicolegal concerns
Intubation Skill

“Skill” (“Proficiency”) = Baseline Training + Regular Application

McGovern Medical School at UTHealth
Intubations Per Paramedic
Pennsylvania 2003

Intubations Per Paramedic
Pennsylvania 2003

Median ETI: 1 (IQR 0-3)
39% performed no ETI
67% performed 2 or fewer ETI

“We Have a Problem . . .”

- Prehospital ETI clinical benefit not proven
- Prone to error
- Difficult
- Interacts with other interventions
- Performed under worst possible conditions
- Limited training
“There is an Alternative…”
Supraglottic Airways (SGA)

- Easier technique
- Less training required
- Similar ventilation to ETI
- Increasing use as primary airway in OHCA
“SGA vs ETI – Unexpected Results”
Endotracheal Intubation Versus Supraglottic Airway Insertion After Out-of-Hospital Cardiac Arrest

Henry E. Wang, MD, MS
Department of Emergency Medicine, University of Alabama at Birmingham
Danny Syzdlo, MS; John Stouffer, EMT-P; Steve Lin, MDCM; Jestin Carlson, MD; Christian Vaillancourt, MD; Gena Sears, BSN; Richard Verbeek, MD; Raymond Fowler, MD; Ahamed Idris, MD; Karl Koenig, EMT-P; James Christenson, MD; Anush Minokadeh, MD; Joseph Brandt, EMT-P; Thomas Rea, MD; and the ROC Investigators
ETI vs. SGA in Cardiac Arrest
ROC PRIMED Trial

10,455 OHCA

8,457 ETI
- 909 King
- 296 Combitube

1,968 SGA
- 239 LMA
- 518 Unknown
ETI Wins over SGA (Oops...)

Wang, Resuscitation 2012
ETI Wins over SGA (Oops...)

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Wang, Resuscitation 2012
ETI wins over SGA (Oops…)

Wang, Resuscitation 2012
ETI vs. SGA
Meta Analysis of Observational Studies

<table>
<thead>
<tr>
<th>Study</th>
<th>N (ETI)</th>
<th>N (SGA)</th>
<th>OR (95% CI)</th>
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</thead>
<tbody>
<tr>
<td>FULL MODEL:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kajino 2011</td>
<td>1679</td>
<td>3698</td>
<td>0.71 (0.39-1.30)</td>
</tr>
<tr>
<td>McMullan 2014</td>
<td>5591</td>
<td>3110</td>
<td>1.66 (1.15-2.41)</td>
</tr>
<tr>
<td>Noda 2007</td>
<td>4</td>
<td>24</td>
<td>5.22 (0.09-299.04)</td>
</tr>
<tr>
<td>Tanabe 2013</td>
<td>12992</td>
<td>29640</td>
<td>1.30 (1.06-1.59)</td>
</tr>
<tr>
<td>Wang 2012</td>
<td>8487</td>
<td>1968</td>
<td>1.40 (1.04-1.89)</td>
</tr>
<tr>
<td>Yanagawa 2010</td>
<td>158</td>
<td>478</td>
<td>1.01 (0.20-5.05)</td>
</tr>
<tr>
<td>TOTAL</td>
<td>28911</td>
<td>38918</td>
<td>1.33 (1.09-1.61)</td>
</tr>
</tbody>
</table>

SENSITIVITY ANALYSIS MODEL:

<table>
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</tr>
<tr>
<td>TOTAL</td>
<td>28749</td>
<td>38416</td>
<td>1.33 (1.04-1.69)</td>
</tr>
</tbody>
</table>

**Outcomes**
Better with Intubation than SGA

Benoit, Resuscitation, 2015
A Randomized Trial is Necessary

• **Confounding-by-indication**

• **Randomization is only way to overcome confounding-by-indication**
“Three Landmark Airway Management Clinical Trials”
Pragmatic Airway Resuscitation Trial (PART)

Wang, et al, JAMA 2018
Laryngeal Tube vs. Endotracheal Intubation in Adult Out-of-Hospital Cardiac Arrest


The University of Texas Health Science Center at Houston, University of Alabama at Birmingham, University of Texas Southwestern Medical Center, Medical College of Wisconsin, University of Pittsburgh, Oregon Health and Science University, University of Washington
Objective

- Compare effectiveness of initial laryngeal tube (LT) vs. initial ETI upon outcomes in adult OHCA
Design

• Multicenter cluster randomized trial with crossover
• Exception from Informed Consent
  – 21 CFR 50.24
• 27 EMS agencies
  – Alabama
  – Dallas-Fort Worth
  – Milwaukee
  – Pittsburgh
  – Portland
Funding Requirements

- NHLBI program for low-cost pragmatic clinical trials
- Pragmatic emphasis
  - Adherence to standard practices
  - Focus on outcomes
  - Less emphasis on mechanisms
- Capped funding ($2.35M)
- US sites only
Enrollment Criteria

Inclusion
• Adult out-of-hospital cardiac arrest
• Treated by EMS
• Requiring advanced airway or BVM

Exclusion
• Children
• Pregnant women
• Prisoners
• Trauma
• Interfacility Transports
• Initial care by non-study EMS agency
• “Do not enroll” bracelet
Interventions

Adult Out-of-Hospital Cardiac Arrest

Laryngeal Tube
  Advanced EMS: LT
  Basic EMS: BVM (or LT)

Endotracheal Intubation
  Advanced EMS: ETI
  Basic EMS: BVM

CONTINUE RESUSCITATION
## Cluster Randomization with Crossover

### Cluster-Crossover Schedule

<table>
<thead>
<tr>
<th>Randomization Cluster</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Dec</td>
<td>Jan</td>
<td>Feb</td>
</tr>
<tr>
<td>K</td>
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<td></td>
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<td>E</td>
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<td>L</td>
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<td>B</td>
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<td>F</td>
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<td>M</td>
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<td>A</td>
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<tr>
<td>I</td>
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</tbody>
</table>

**Legend:**
- **LT** (Light Treatment)
- **ETI** (Electrotherapy Intervention)
Outcomes

• Primary outcome → 72-hour survival
  – Pragmatic considerations
  – Limitations of funding

• Secondary outcomes
  – ROSC on ED arrival
  – Survival to hospital discharge
  – Favorable neurologic outcome on hospital discharge (MRS≤3)
  – Airway management course, adverse events
Data Analysis

• **Intention-to-treat**
  – Generalized estimating equations
  – Accounted for randomization cluster and interim analyses

• **Other analyses**
  – *A priori* defined subgroups
  – *Per-protocol* and *as-treated* analyses
  – *Post-hoc* multivariable adjusted analyses

• **Sample size estimate**
  – Data from ROC PRIMED trial
  – Power 85%, alpha 0.05, 5% loss in precision due to clustering, 4.5% difference in 72h survival
  – Estimated minimum sample size 2,612
  – Increased sample size to **3,000**
Results

56 Cluster Enrollment Periods

30 LT Periods
1,968 Patients Screened
463 Patients Excluded
1,505 Patients Assigned to LT

26 ETI Periods
1,872 Patients Screened
373 Patients Excluded
1,499 Patients Assigned to ETI
### Patient Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>LT (N=1,505)</th>
<th>ETI (N=1,499)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age – years, median (IQR)</td>
<td>64 (53, 76)</td>
<td>64 (53, 76)</td>
</tr>
<tr>
<td>Male</td>
<td>61.7%</td>
<td>60.1%</td>
</tr>
<tr>
<td>EMS Witnessed Arrest</td>
<td>13.3%</td>
<td>12.8%</td>
</tr>
<tr>
<td>Bystander Witnessed Arrest</td>
<td>37.7%</td>
<td>37.8%</td>
</tr>
<tr>
<td>Bystander CPR</td>
<td>55.5%</td>
<td>55.4%</td>
</tr>
<tr>
<td>EMS Dispatch-to-Arrival – minutes, med (IQR)</td>
<td>2.1 (1.1, 3.8)</td>
<td>2.1 (1.0, 3.7)</td>
</tr>
<tr>
<td>Shockable ECG Rhythm</td>
<td>20.0%</td>
<td>18.0%</td>
</tr>
<tr>
<td>Epinephrine Given</td>
<td>92.0%</td>
<td>93.7%</td>
</tr>
<tr>
<td>Transported to Hospital</td>
<td>60.2%</td>
<td>59.3%</td>
</tr>
<tr>
<td>Hospital Therapeutic Hypothermia</td>
<td>52.6%</td>
<td>46.3%</td>
</tr>
<tr>
<td>Hospital Coronary Catheterization</td>
<td>23.7%</td>
<td>18.3%</td>
</tr>
</tbody>
</table>

Similar Between Groups
Airway Management Characteristics

- Protocol Compliance
  - Arrive → Airway Start (min)
  - 90.7% to 95.5%

- Initial Airway Success
  - 51.3% to 89.9%

- Overall Airway Success
  - 91.5% to 94.2%

- ED Intubation
  - 33.1% to 64.4%
Airway Management Characteristics

- Protocol Compliance:
  - Arrive → Airway Start (min): 11.0
  - Overall Airway Success: 91.5%

- Initial Airway Success:
  - Arrive → Airway Start (min): 13.6
  - Overall Airway Success: 94.2%

- Overall Airway Success:
  - Arrive → Airway Start (min): 11.0
  - Overall Airway Success: 94.2%

- ED Intubation:
  - Arrive → Airway Start (min): 13.6
  - Overall Airway Success: 64.4%
Airway Management Characteristics

- Protocol Compliance: 90.7% compliance, 95.5% success
- Initial Airway Success: 51.3% of arrivals, 89.9% success
- Overall Airway Success: 91.5% of arrivals, 94.2% success
- ED Intubation: 33.1% of cases, 64.4% success

Arrive → Airway Start (min):
- Arrival: 11.0 minutes
- Intubation: 13.6 minutes
### Primary and Secondary Outcomes

#### 72h Survival
- **LT**: 18.3%
- **ETI**: 15.4%

\[ \Delta = 2.9\% (0.2\%-5.6\%) \]

\[ P=0.04 \]

#### ROSC
- **LT**: 27.9%
- **ETI**: 24.3%

\[ \Delta = 3.6\% (0.3\%-6.8\%) \]

\[ P=0.03 \]

#### Hospital Discharge
- **LT**: 10.8%
- **ETI**: 8.1%

\[ \Delta = 2.7 (0.6\%-4.8) \]

\[ P=0.01 \]

#### Favorable Neuro Status
- **LT**: 7.1%
- **ETI**: 5.0%

\[ \Delta = 2.1\% (0.3\%-3.8\%) \]

\[ P=0.02 \]
Primary and Secondary Outcomes

72h Survival

- LT: 18.3%
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Δ = 2.9% (0.2-5.6%)  
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ROSC

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Δ = 2.7 (0.6-4.8)  
P=0.01

Favorable Neuro Status

- LT: 7.1%
- ETI: 5.0%

Δ = 2.1% (0.3-3.8%)  
P=0.02

"LT better than ETI over all outcomes"
Airways-2 Trial

Benger, et al, JAMA 2018
Airways-2 Design

• RCT
• United Kingdom
  • 4 EMS agencies
  • Population 21 million
  • 40% of UK population
• Adult OHCA
• Intubation vs i-gel

• Cluster randomized
  • By study paramedic
  • N=1,523 medics
• Hospital Survival with Favorable Neuro Status
• Estimated n=9,070 patients
• June 2015 – August 2017
### Airways-2 – Primary Findings

<table>
<thead>
<tr>
<th></th>
<th>No. of Patients/Total No.²</th>
<th>Adjusted Odds Ratio (95% CI)</th>
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<tr>
<td></td>
<td>Tracheal Intubation</td>
<td>Supraglottic Airway Device</td>
</tr>
<tr>
<td>Primary analysis for modified Rankin Scale scoreᵇ</td>
<td>300/4407</td>
<td>311/4882</td>
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<tr>
<td>Subgroup analysis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Utstein comparatorᶜ</td>
<td>154/697</td>
<td>177/764</td>
</tr>
<tr>
<td>Utstein noncomparatorᶜ</td>
<td>130/3658</td>
<td>123/4067</td>
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<tr>
<td>Out-of-hospital cardiac arrest witnessed by paramedicᵉ</td>
<td>87/556</td>
<td>76/607</td>
</tr>
<tr>
<td>Out-of-hospital cardiac arrest not witnessed by paramedicᵉ</td>
<td>212/3848</td>
<td>235/4271</td>
</tr>
<tr>
<td>Sensitivity analysis for primary outcomeᶠ</td>
<td>300/10741</td>
<td>311/11462</td>
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*P Value*

- .33
- .24ᵈ
- .24ᵈ
- .63

Odds Ratio (95% CI)
Airways-2 – Primary Findings

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</tr>
<tr>
<td>Utstein noncomparator</td>
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<td>0.84 (0.65-1.09)</td>
<td>.24d</td>
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<td>0.78 (0.55-1.09)</td>
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<td>0.96 (0.81-1.14)</td>
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“No difference between i-gel and ETI”
Important Secondary Finding

• ~18% received BVM only

• When limited to 7,576 receiving i-Gel or ETI:
  • i-gel → 163 of 4,158 (3.9%) good outcome
  • ETI → 88 of 3,418 (2.6%) good outcome
  • Risk difference 1.4% (95% CI: 0.5-2.2%)
Important Secondary Finding

• ~18% received BVM only

• When limited to 7,576 receiving i-Gel or ETI:
  • i-gel → 163 of 4,158 (3.9%) good outcome
  • ETI → 88 of 3,418 (2.6%) good outcome
  • Risk difference 1.4% (95% CI: 0.5-2.2%)

“Per-Protocol → i-gel better than ETI”
Cardiac Arrest Airway Management Trial (CAAM)

Jabre, et al., JAMA 2018
CAAM Design

- RCT
- France and Belgium SAMUs
  - 20 EMS centers
  - MD + RN + Driver
- Adult OHCA
- BVM vs. ETI
  - Intervention by “medical team”
  - ETI post-ROSC

- Per-Patient Randomization
  - Sealed envelopes
- 28d Survival with Favorable Neuro Status
- “Non-inferiority” design
  - 1% Non-inferiority margin
  - Estimated n=2,000
- March 2015 - Jan 2017
Primary Result
28-day Survival with Favorable Neuro Status (CPC 1-2)

- BVM → 44 / 1018 (4.3%)
- ETI → 43 / 1022 (4.2%)
- Difference = 0.11% (1-sided 97.5% CI: -1.64% to infinity)
- Non-inferiority p=0.11
Primary Result
28-day Survival with Favorable Neuro Status (CPC 1-2)

• BVM → 44 / 1018 (4.3%)
• ETI → 43 / 1022 (4.2%)
• Difference = 0.11% (1-sided 97.5% CI: -1.64% to infinity)
• Non-inferiority p=0.11

“This is an uninterpretable result...”
### Table 3. Airway Management Adverse Events Analysis

<table>
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<tr>
<th>Safety Population</th>
<th>BMV Group</th>
<th>ETI Group</th>
<th>Absolute Difference, BMV(%) – ETI(%) (95% CI)</th>
<th>P Value^a</th>
</tr>
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<tbody>
<tr>
<td><strong>BMV or ETI Difficulty</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMV VAS, median (IQR), mm^b</td>
<td>20 (5-55)</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Intubation Difficulty Scale score, median (IQR)</td>
<td>NA</td>
<td>1 (0-4)</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Rate of airway management difficulty, No./total No. (%)^c</td>
<td>186/1027 (18.1)</td>
<td>134/996 (13.4)</td>
<td>4.7 (1.5-7.9)</td>
<td>.004</td>
</tr>
<tr>
<td>BMV or ETI failure, No./total No. (%)</td>
<td>69/1028 (6.7)</td>
<td>21/996 (2.1)</td>
<td>4.6 (2.8-6.4)</td>
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# Very Important Secondary Findings

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<tr>
<th>Safety Population</th>
<th>BMV Group</th>
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<th>Absolute Difference, BMV(%) - ETI(%) (95% CI)</th>
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<tr>
<td>Intubation Difficulty Scale score, median (IQR)</td>
<td>NA</td>
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<td>NA</td>
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## Summing Up the Trials

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<th>PART</th>
<th>Airways-2</th>
<th>CAAM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Setting</td>
<td>USA</td>
<td>UK</td>
<td>France, Belgium</td>
</tr>
<tr>
<td>Comparison</td>
<td>LT vs. ETI</td>
<td>i-gel vs. ETI</td>
<td>BVM vs. ETI</td>
</tr>
<tr>
<td>Practitioners</td>
<td>Paramedics, Some EMTs</td>
<td>Paramedics</td>
<td>Physicians (SAMUs)</td>
</tr>
<tr>
<td>Sample Size</td>
<td>3,000</td>
<td>9,296</td>
<td>2,043</td>
</tr>
<tr>
<td>Randomization</td>
<td>Cluster Randomized by EMS Agencies</td>
<td>Cluster Randomized by Medic</td>
<td>Per Patient (sealed envelopes)</td>
</tr>
<tr>
<td>Primary Outcome</td>
<td>72-hour Survival</td>
<td>Hospital Survival w/Favorable Neuro Status</td>
<td>28-Day Survival w/Favorable Neuro Status</td>
</tr>
<tr>
<td>BVM-only rate</td>
<td>~12%</td>
<td>~18%</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Primary Finding</strong></td>
<td>LT better than ETI</td>
<td>No difference between i-gel and ETI</td>
<td>Inconclusive</td>
</tr>
<tr>
<td>Important Secondary Findings</td>
<td>Low ETI Success Rate</td>
<td>i-gel Better Than ETI</td>
<td>BVM → Poorer Ventilation, Higher Aspiration</td>
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The Big Picture

• PART  “SGA (LT) is better than ETI”

• Airways-2  “At best, ETI is no better than SGA (i-Gel)”

• CAAM  “BVM is not the answer”
Next Chapters

- Mechanistic data
  - Chest compressions
  - Lung ventilations
- SGA Safety Data
- Implementation strategies
- Other patient groups
  - Trauma (PACT)
  - Peds (Pedi-PART)
- Hospital airway practices
Questions?

Henry E. Wang, MD, MS
Department of Emergency Medicine
The University of Texas Health Science Center at Houston
Henry.e.wang@uth.tmc.edu